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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,886 | 02/01/2005 | Shin Shimaoka | SHIMAOKA1 | 6595 |

1444 7590 09/29/2006

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EXAMINER

QAZI, SABIHA NAIM

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/522,886

Applicant(s)

SHIMAOKA, SHIN

Examiner

Sabiha Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/23/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Non-Final Office Action

Claims 3, 4 and 6 are pending. No claim is allowed at this time. Acknowledgment is made of the response filed on 8/23/2006

Summary of this Office Action dated Thursday, Sept. 21, 2006

1. Invention
2. Response to Remarks
3. 35 USC § 102(b) Rejection
4. 35 USC § 103(a) Rejection
5. Communication

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Invention

Presently claimed invention is drawn for the treatment of psoriasis by the compound of formula (I) in claim

1. This compound is a known compound and named as ED-71, which is 1 α , 25-dihydroxy-2 α (3-hydroxypropoxy) vitamin D₃.

Response to Remarks

- Applicant's arguments are found persuasive therefore rejection is withdrawn. Upon further review and search new rejections are being made. Finality of the rejection is withdrawn.
- Arguments are moot because rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by KOST¹ et al. See claims 11 and 14 on page 18, claims 19, 21, 25, and 26 on page 19 where E-D71 has been disclosed for treatment of psoriasis. Method of treating psoriasis by ED-71 (1 α , 25-dihydroxy-2 α (3-hydroxypropoxy) vitamin D₃), which is presently claimed, is disclosed by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over ONO et al.¹ and KOSH et al. The references teach 2-substituted hydroxypropyl vitamin D3 and other analogues for the treatment of psoriasis, which embraces Applicant's claimed invention.

¹ WO 96/00074

² Chem. Pharm. Bull 45, (10), 1626-1630 (1997)

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Ono et al. teaches $1\alpha,25$ -dihydroxy- 2α (3-hydroxypropoxy) vitamin D_3 useful for the treatment of osteoporosis. Furthermore it teaches that vitamin D analogues are useful for the treatment of psoriasis, cancer, and various other diseases. See the entire document especially compounds 3, 4 and 5 and paragraphs 1-4 on page 1626. The compound $1\alpha,25$ -dihydroxy- 2α (3-hydroxypropoxy) vitamin D_3 (ED-71), compound no. 4 increased the plasma levels in rats on low Ca/D-deficient diet more significantly than $1,25$ -dihydroxyvitamin D_3 (compound 1).

ONO does not teach specifically the treatment of psoriasis by ED-71.

KOSH teaches a method of treating psoriasis by ED-71 ($1\alpha, 25$ -dihydroxy- 2α (3-hydroxypropoxy) vitamin D_3), which is presently claimed. See the entire document especially 7-10 and last paragraph on page 2; lines line 16 on page 4; claims 11 and 14 on page 18, claims 19, 21, 25, and 26 on page 19 where E-D71 has been disclosed for treatment of psoriasis. The reference teach oral and transdermal administration. See claims 25 and 26)

Instant claims differ from the reference in claiming the treatment and agent for psoriasis wherein the reference teaches the use of the same compound for the treatment of osteoporosis, psoriasis and various other diseases.

It would have been obvious to one skilled in the art at the time of invention to treat psoriasis by (ED-71) $1\alpha,25$ -dihydroxy- 2α , (3-hydroxypropoxy) vitamin D_3 . Prior art teaches that this compound has very low calcemic effects and is useful for the treatment of psoriasis (summary of invention on page2). The references further teach that the compound may be administered orally or transdermally. The reference teaches all the limitations of claimed invention. Motivation has been provided by the prior art to prepare additional beneficial composition useful for the treatment of psoriasis by using the compound ED-71 as presently claimed. No new concept was noted.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).


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Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SABIHA QAZI, PH.D.
PRIMARY EXAMINER